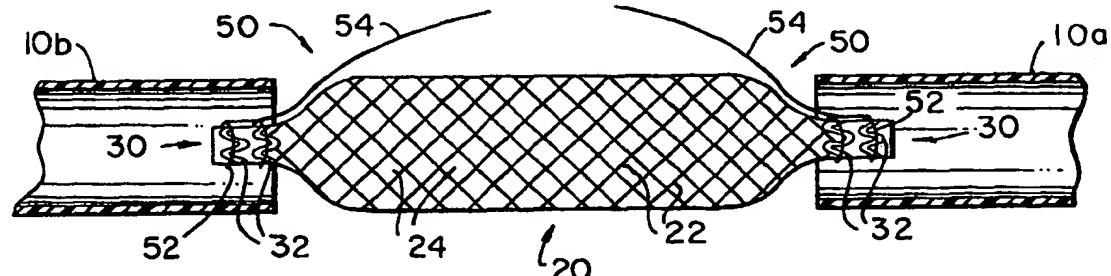




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(54) Title: ARTIFICIAL MEDICAL GRAFT METHODS AND APPARATUS  (57) Abstract <p>A tubular artificial graft for attachment to a patient's tubular body tissue has an initially radially relatively small connector structure adjacent each of its ends. The initial relatively small size of each connector structure facilitates insertion of that portion of the graft into the body tissue to which that connector structure is to make a connection. After a connector structure is properly positioned relative to the body tissue, the connector structure is radially enlarged to connect the graft to the body tissue. The connection is preferably both a mechanical and a fluid-tight connection.</p>		

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ARTIFICIAL MEDICAL GRAFT
METHODS AND APPARATUS

Background of the Invention

5 This invention relates to medical apparatus
and procedures, and more particularly to artificial
medical graft methods and apparatus.

Tubular artificial grafts are needed in
various medical procedures. For example, such grafts
may be needed to replace diseased or damaged sections
10 of natural tubular body tissue such as in the
circulatory system, the urinary tract, etc. Or such
grafts may be needed to make new connections in natural
tubular body tissue systems such as bypass or shunt
connections in the circulatory system. An artificial
15 tubular graft may be needed as either a temporary or
permanent installation.

Important considerations regarding the use of
artificial grafts include ease of use, time required
for installation, secureness of installation, and
20 performance after installation. Improvements are
constantly sought in all of these areas.

In view of the foregoing, it is an object of
this invention to provide improved artificial grafts.

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It is another object of this invention to provide improved methods and apparatus for installing medical grafts.

Summary of the Invention

5 These and other objects of the invention are accomplished in accordance with the principles of the invention by providing artificial tubular grafts that have axial end portions that are initially radially relatively small, but that can be radially enlarged
10 when desired. In their initially radially relatively small condition, the axial end portions of the graft are easily inserted into the ends of or other apertures in the natural body tissue tubes to be connected. Once each axial end portion of the graft is properly
15 positioned in the appropriate natural body tissue tube, that end portion is radially enlarged to securely engage the tissue tube. In addition to providing mechanical attachment of the artificial graft to the body tissue tube, the radial enlargement of the graft end portions provides a fluid-tight seal between the
20 graft and the body tissue tubes. Various techniques may be used for radially expanding the end portions of the graft. The graft may be augmented with various types of connectors or fasteners for helping to ensure
25 good mechanical and fluid-tight connection between the graft and the body tissue.

Further features of the invention, its nature, and various advantages will be more apparent from the accompanying drawings and the following
30 detailed description of the preferred embodiments.

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Brief Description of the Drawings

FIG. 1 is a simplified elevational view of an illustrative embodiment of an artificial graft and illustrative apparatus useful in installing the graft, all in accordance with this invention. FIG. 1 shows the graft being installed between the ends of two sections of natural body tissue tubing.

FIG. 2 is a simplified elevational view of an illustrative embodiment of a portion of the apparatus shown in FIG. 1.

FIG. 3 is a view similar to FIG. 1 showing the installed graft.

FIG. 4 is a simplified end view of an illustrative embodiment of a portion of the apparatus shown in FIG. 3.

FIG. 5 is a simplified end view of another illustrative embodiment of a portion of the apparatus shown in FIG. 3.

FIG. 6 is an elevational view of a structure that can be used to make a particular embodiment of the apparatus portion shown in FIG. 4.

FIG. 7 is a simplified elevational view of a subsequent condition of the FIG. 6 structure during fabrication.

FIG. 8 is another view generally similar to FIG. 1, but showing another illustrative embodiment of the invention.

FIG. 9 is a view similar to FIG. 8 showing a later stage in use of the FIG. 8 apparatus.

Detailed Description of the Preferred Embodiments

In the illustrative embodiment shown in FIG. 1, artificial tubular graft 20 is being installed

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between the ends of two sections 10a and 10b of natural body tissue tubing in a patient. For example, the purpose of graft 20 may be to replace a diseased or damaged portion of the patient's body tissue tubing that has been removed. Tubing 10 may be circulatory system tubing or any other body tissue tubing that is suitable for use with graft 20.

Although any suitable construction can be used for the main portion of graft 20, a particularly preferred construction is shown and described in Goldsteen et al. U.S. patent application No. 08/745,618, filed November 7, 1996, which is hereby incorporated by reference herein in its entirety. For example, this graft construction may include a tubular mesh framework 22 of nitinol covered with silicone 24 to substantially fill in the interstices in the framework. Additional details, features, and alternatives regarding this type of graft construction will be found in the above-mentioned Goldsteen et al. reference, and in Bachinski et al. U.S. patent application No. 08/839,080, filed April 23, 1997, which is also hereby incorporated by reference herein in its entirety. For present purposes, it will be sufficient to point out that grafts having this type of construction are extremely elastic and that they can be radically deformed without damage or permanent change in shape. They can be made with any desired porosity (e.g., through the silicone). For use in the circulatory system, they can also be made so that they pulse in response to pressure pulses in the blood flowing through them, very much like the pulsation of natural blood vessels. This can be important to discouraging the formation of clots in the graft.

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In accordance with the present invention, each axial end portion of graft 20 includes a radially enlargeable connector structure 30. In embodiments of the type shown in FIG. 1, each connector structure 30 is self-expanding. In other words, each connector structure 30 is an elastic, annular structure which is resiliently biased to return to a radially enlarged size that is preferably at least as large as (and more preferably somewhat larger than) the body tissue tube opening to which that end portion of the graft will be attached. Initially, however, each connector structure 30 is radially compressed to a substantially smaller size as shown in FIG. 1. This allows each axial end portion of graft 20 to be easily inserted (as shown in FIG. 1) into the body tissue tubing 10 to which that end portion of the graft is to be attached.

In the particular embodiment shown in FIG. 1, the initial radial compression of each connector structure 30 is maintained by a clip structure 50 on that connector structure. Each clip structure 50 includes a clip portion 52 and a release portion 54 (see also FIG. 2). For example, each clip structure 50 may be made of stainless steel, with the clip portion 52 being strong enough to radially compress the associated connector structure 30. However, when the release portion 54 of either clip structure 50 is pulled radially out from graft 20, the C-shaped clip portion 52 of that clip structure comes off the associated connector structure 30. This allows the associated connector structure to resiliently radially expand into firm contact with the inner surface of the surrounding body tissue tubing 10 as shown in FIG. 3. This firm contact provides a fluid-tight seal between

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body tissue 10 and graft 20, as well as secure mechanical attachment of the graft to the tissue.

As an alternative to depicted clip structures 50, each connector structure 30 may be initially
5 radially compressed by a wire wrapped around the connector structure. When it is desired to radially enlarge the connector structure, the wire is unwrapped from that structure.

Many other types of removable retaining
10 structures are possible as alternatives to clip structures 50 or the above-mentioned wire wrapping for initially radially compressing connector structures 30. For example, spring-loaded clamps can be used, and such clamps can be provided with lever-type opening arms, or
15 such clamps can be adapted for opening with a pliers-type or forceps-type instrument.

Connector structures 30 may have any of a large number of constructions. For example, each connector structure 30 may include one or more
20 annularly compressible, serpentine-shaped, metal rings 32 (e.g., of nitinol). When such a ring is annularly compressed (e.g., as shown in FIG. 1), the serpentine convolutions of the ring become more sharply curved and closer together). When such a ring is released to
25 return to a more nearly relaxed state, the convolutions of the ring become somewhat straighter. If graft 20 is made of a metal (e.g., nitinol) framework 22 with a covering 24 (e.g., of silicone), rings 32 may be integral with framework 22, and covering 24 may
30 continue into the vicinity of rings 32. Rings 32 may be formed to press substantially uniformly out against the inner surface of body tissue tubing 10 all the way around the circumference of the graft. Alternatively, rings 32 may be formed with circumferentially spaced

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"high spots" or "pressure points" 34 (see FIG. 4) which locally bear somewhat more strongly on the inner surface of body tissue tubing 10. Such localized points 34 of higher bearing pressure and therefore
5 greater indentation of body tissue tubing 10 can help ensure that the end portion of the graft does not slip out of the body tubing after the graft has been installed.

Any construction of connector structures 30
10 may additionally include structures 36 (see FIG. 5) which radially penetrate the adjacent body tissue tubing 10. If such tissue-piercing structures 36 are provided, they may be substantially straight prongs or struts, curved hooks, or any other suitably shaped
15 members. If provided, structures 36 may be sharply pointed to facilitate tissue penetration, and they may be barbed (e.g., like fishing hooks) to substantially prevent them from coming out of the tissue they have pierced.

20 A particularly preferred way of producing a serpentine ring 32 with the above-described high spots 34 is to start with a short length of thin-walled metal tubing 60 as shown in FIG. 6 and cut away interdigitated portions 62 from opposite axial ends of
25 the tube as shown in FIG. 7. The resulting structure is then radially enlarged and annealed. In its radially enlarged form, the structure has the general appearance shown in FIG. 4 when viewed from an axial end. Each point 34 is adjacent an axial end of the
30 original tube 60. The structure can be resiliently radially compressed to the size of the original tube 60 or an even smaller size, and it will return to the radially enlarged size and shape whenever released from radial compression.

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In the alternative embodiment shown in FIG. 8 each connector structure 130 contains a dilatation balloon 140 connected to an associated inflation device 144 by an associated tube 142. (Elements in the FIG. 8 embodiment that are the same as or similar to elements in the previously described embodiments have reference numbers that are increased by 100 from the reference numbers used for the corresponding elements in the previously described embodiments.) Each of tubes 142 may pass through an aperture 126 in the side wall of tubular graft 120. Each of apertures 126 may be provided with a purse string suture 128 or other functionally equivalent structure for use in closing the aperture when desired.

Balloons 140 are initially uninflated so that connector structures 130 can be initially radially relatively small as shown in FIG. 8. As in the case of FIG. 1, the initially relatively small radial size of connector structures 130 facilitates their insertion in the body tissue tubing 10a and 10b to which graft 120 is to be attached. Each connector structure 130 may be a structure which is plastically deformable to a radially relatively large size by inflation of the associated balloon 140. Alternatively, each connector structure 130 may be a radially compressed, self-expanding structure that is releasably held in a radially compressed state by an associated frangible structure. When additional radial enlarging force is exerted by inflation of the associated balloon 140, the frangible structure breaks and the connector structure 130 returns resiliently to a radially enlarged size.

FIG. 9 shows inflation of balloons 140 to radially enlarge connector structures 130, either by plastically deforming the connector structures or by

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releasing the connector structures from frangible or other similar restraints. When radially enlarged as shown in FIG. 9, connector structures 130 engage the surrounding body tissue 10 and form a fluid-tight seal and mechanical attachment between the body tissue and graft 120. Connector structures 130 may have any of the constructions and/or features described above in connection with structures 30 (e.g., with reference to FIGS. 4-7) for helping to ensure good mechanical and fluid-tight connections between body tissue 10 and graft 120.

After graft 120 has been installed by inflation of balloons 140 as shown in FIG. 9, balloons 140 are deflated again. Then tubes 142 and balloons 140 are withdrawn from graft 120 via apertures 126. After apertures 126 have thus been cleared, apertures 126 are closed (e.g., by tightening and securing purse string sutures 128). Except for the addition of closed apertures 126, the appearance of finished and fully installed graft 120 may be substantially as shown for graft 20 in FIG. 3.

Grafts 20/120 are preferably made up in a range of sizes (e.g., lengths and diameters) so that they are available for various patient applications. Grafts 20/120 may also be made in a variety of shapes, and these various shapes may also be made in a range of sizes. For example, grafts 20/120 may be made in curved shapes, Y shapes, T shapes, etc. In the case of shapes with more than two ports (e.g., Y or T shapes with three ports), each port is provided with a connector structure 30/130 for attachment of that port to body tissue of the patient. References to "tubular grafts" herein include such graft structures with more than two ports. References herein to "ends" or "end

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portions" of grafts refer to the port regions of grafts, regardless of the shape or number of ports of the graft.

It will be understood that the foregoing is
5 only illustrative of the principles of this invention and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the number of rings 32 used in each of connector structures 30/130
10 can differ from the number employed in the embodiments shown herein. Other possible constructions or features of connector structures 30/130 are shown in Bachinski et al. U.S. patent application No. 08/839,199, filed April 23, 1997, which is hereby incorporated by
15 reference herein in its entirety. In embodiments of the type shown in FIGS. 8 and 9, structures other than balloons 140 may be used for radially enlarging connector structures 130. For example, a radially enlargeable mechanical structure somewhat like a
20 reversely operating pair of pliers or a reversely operating forceps may be used inside each connector structure 130 to radially enlarge the connector structure. Although illustrative grafts 20/120 are shown connecting ends of body tissue tubing 10, it will
25 be understood that the grafts of this invention are equally useful in making connections to body tissue tubing through apertures (e.g., incisions) in the side walls of body tissue tubing.

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The Invention Claimed Is

1. A tubular graft comprising:
a tubular connection portion which is initially radially relatively small and which is selectively radially enlargeable.
2. The graft defined in claim 1 wherein the connection portion is configured to selectively resiliently radially enlarge from being radially relatively small.
3. The graft defined in claim 2 further comprising:
a releasable retainer configured to retain the connection portion radially relatively small until the retainer releases the connection portion.
4. The graft defined in claim 3 wherein the retainer comprises:
a removable structure disposed at least part way around the connector portion.
5. The graft defined in claim 4 wherein the removable structure comprises:
a C-shaped clip structure.
6. The graft defined in claim 2 wherein the connection portion comprises:
an initially radially compressed annular structure.

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7. The graft defined in claim 6 wherein the annular structure is serpentine-shaped in the annular direction.

8. The graft defined in claim 7 wherein the annular structure is radially compressed at least in part by increasing the curvature of the serpentine shape.

9. The graft defined in claim 6 wherein the annular structure comprises a plurality of projecting portions which project radially outward beyond the remainder of the annular structure at least when the connection portion is radially enlarged.

10. The graft defined in claim 9 wherein the projecting portions are configured to penetrate body tissue to which the graft is connected.

11. The graft defined in claim 6 wherein the annular structure is formed from a tube from which interdigitated portions that extend in from the axial ends of the tube have been removed.

12. The graft defined in claim 2 wherein the connection portion is configured to selectively plastically radially enlarge from being radially relatively small.

13. The graft defined in claim 12 wherein the connection portion comprises:
an initially radially compressed annular structure.

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14. The graft defined in claim 13 wherein the annular structure is serpentine-shaped in the annular direction.

15. The graft defined in claim 14 wherein the annular structure is radially compressed at least in part by increasing the curvature of the serpentine shape.

16. The graft defined in claim 13 wherein the annular structure comprises a plurality of projecting portions which project radially outward beyond the remainder of the annular structure at least when the connection portion is radially enlarged.

17. The graft defined in claim 16 wherein the projecting portions are configured to penetrate body tissue to which the graft is connected.

18. The graft defined in claim 14 wherein the annular structure is formed from a tube from which interdigitated portions that extend in from the axial ends of the tube have been removed.

19. The graft defined in claim 12 further comprising:

a selectively radially enlargeable structure disposed in the connection portion and configured to selectively radially enlarge the connection portion.

20. The graft defined in claim 19 wherein the radially enlargeable structure comprises:

a selectively inflatable balloon.

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21. The graft defined in claim 19 wherein the radially enlargeable structure is controlled via a control structure which passes through a wall of the graft.

22. The graft defined in claim 21 wherein the radially enlargeable structure and the control structure are removable from the graft by withdrawing them through the wall of the graft.

23. The graft defined in claim 22 further comprising:

a structure configured to close the wall of the graft where the radially enlargeable structure and the control structure are removed from the graft through that wall.

24. The graft defined in claim 1 further comprising:

a selectively radially enlargeable structure for selectively radially enlarging the connection portion.

25. The graft defined in claim 24 wherein the radially enlargeable structure is controlled via a control structure which passes through an aperture in a tubular side wall of the graft.

26. The graft defined in claim 25 wherein the radially enlargeable structure and the control structure are configured to be withdrawn via the aperture.

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27. The graft defined in claim 26 further comprising:

a structure configured to selectively close the aperture.

28. The graft defined in claim 24 wherein the radially enlargeable structure comprises:

a selectively inflatable balloon.

29. The graft defined in claim 1 wherein the connection portion comprises:

a plurality of projecting portions which project radially outward beyond the remainder of the connection portion at least when the connection portion is radially enlarged.

30. The graft defined in claim 29 wherein the projecting portions are configured to penetrate body tissue to which the graft is connected.

31. The graft defined in claim 1 wherein the connection portion comprises:

an initially radially compressed annular structure.

32. The graft defined in claim 31 wherein the annular structure is serpentine-shaped in the annular direction.

33. The graft defined in claim 32 wherein the annular structure is radially compressed at least in part by increasing the curvature of the serpentine shape.

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34. The graft defined in claim 33 wherein the annular structure is radially enlarged at least in part by decreasing the curvature of the serpentine shape.

35. The graft defined claim 1 further comprising:

a tubular framework extending axially from the connection portion; and
a covering on the tubular framework.

36. The graft defined in claim 35 wherein the framework comprises:
a metal mesh.

37. The graft defined in claim 36 wherein the metal comprises nitinol.

38. The graft defined in claim 35 wherein the covering comprises silicone.

39. A method of installing a tubular graft in a patient in order to make a fluid connection between at least two portions of the patient's body tissue tubing, said graft having axially spaced portions which are initially radially relatively small, comprising:

inserting each of the axially spaced portions of the graft in a respective one of the portions of the patient's body tissue tubing; and
radially enlarging each of the axially spaced portions of the graft in order to cause each of those portions to engage the surrounding body tissue tubing.

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40. The method defined in claim 39 wherein at least one of the initially radially relatively small portions of the graft is releasably radially self-enlargeable to the size required to engage the surrounding body tissue tubing, and wherein the radially enlarging comprises:

releasing the self-enlargeable portion of the graft so that it will radially self-enlarge into engagement with the surrounding body tissue tubing.

41. The method defined in claim 40 wherein the self-enlargeable portion of the graft is initially at least partly surrounded by a retainer for maintaining the self-enlargeable portion radially relatively small, and wherein the releasing comprises:

removing the retainer from the self-enlargeable portion.

42. The method defined in claim 40 wherein the self-enlargeable portion of the graft is initially kept radially relatively small by a frangible retainer, and wherein the releasing comprises:

breaking the retainer.

43. The method defined in claim 39 wherein at least one of the initially radially relatively small portions of the graft is plastically radially enlargeable to the size required to engage the surrounding body tissue tubing, and wherein the radially enlarging comprises:

plastically deforming the plastically enlargeable portion so that it radially enlarges into engagement with the surrounding body tissue tubing.

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44. The method defined in claim 43 wherein a radially enlargeable structure is disposed in the plastically enlargeable portion, and wherein the plastically deforming comprises:

radially enlarging the radially enlargeable structure.

45. The method defined in claim 39 wherein at least one of the initially radially relatively small portions of the graft includes tissue-penetrating structures which project outward from the remainder of that portion of the graft at least when that portion of the graft is radially enlarged to engage the surrounding body tissue, and wherein the radially enlarging comprises:

penetrating the surrounding body tissue with the tissue-penetrating structures.

46. The method defined in claim 39 wherein at least one of the initially radially relatively small portions of the graft contains a selectively radially enlargeable structure, and wherein the radially enlarging comprises:

radially enlarging the radially enlargeable structure.

47. The method defined in claim 46 further comprising:

after the radially enlarging of the radially enlargeable structure, radially reducing the radially enlargeable structure.

48. The method defined in claim 46 wherein the radially enlargeable structure is controlled via a

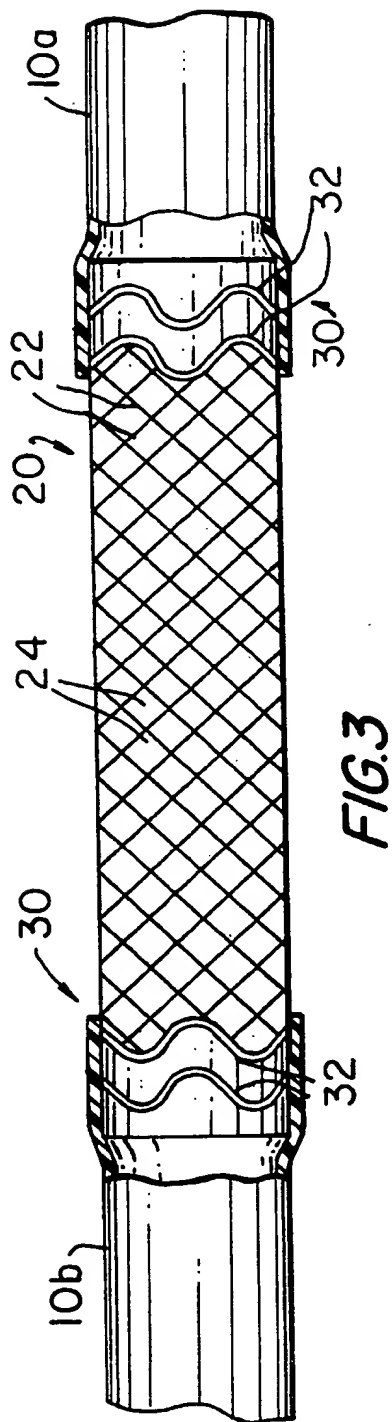
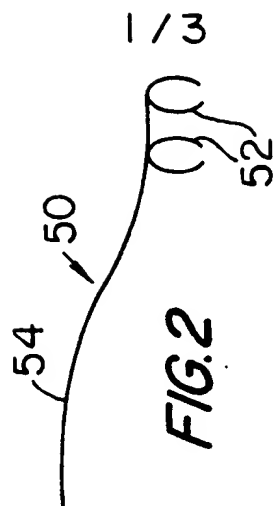
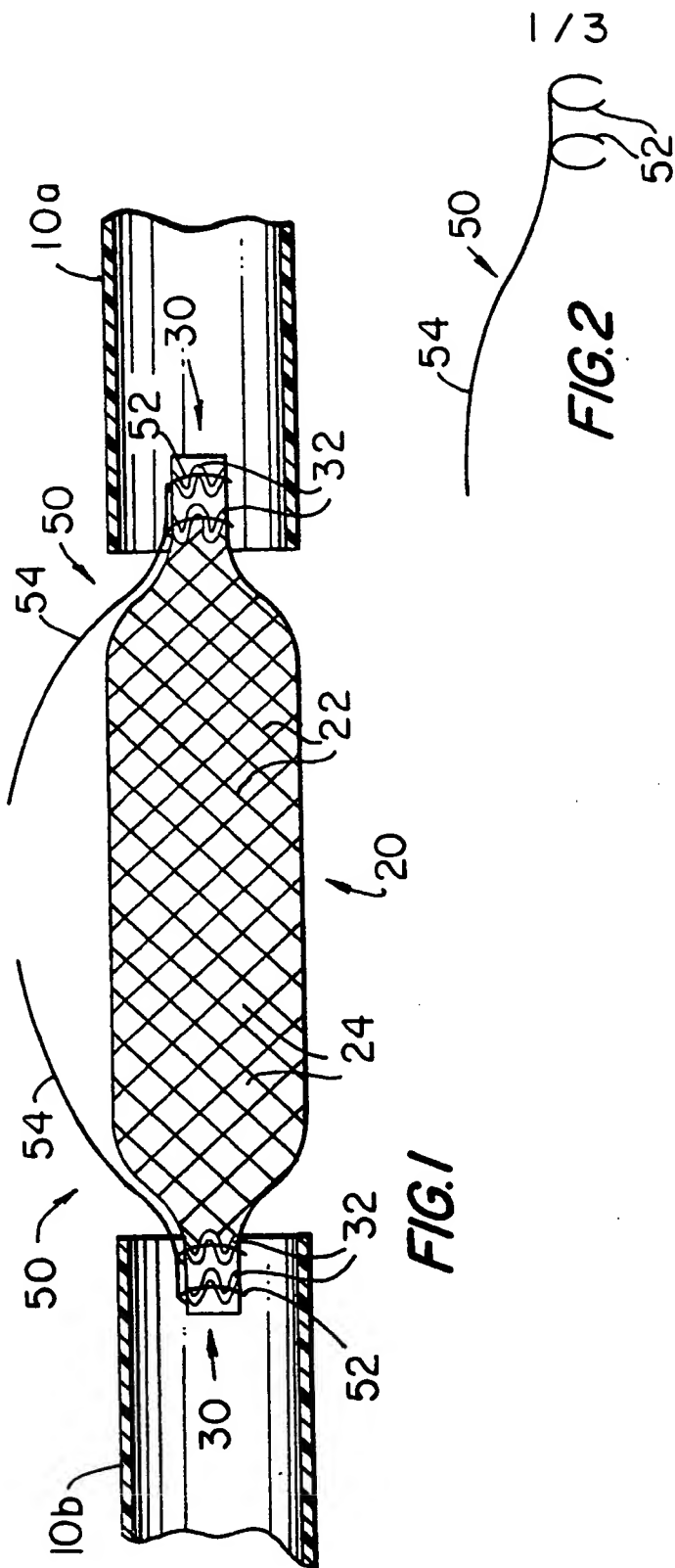
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control structure which passes through an aperture in a side wall of the graft, and wherein said method further comprises:

after the radially enlarging of the radially enlargeable structure, withdrawing the control structure and the radially enlargeable structure from the graft via the aperture.

49. The method defined in claim 48 further comprising:

after the withdrawing, closing the aperture.



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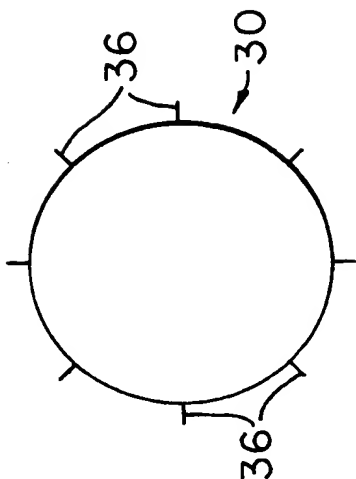


FIG. 5

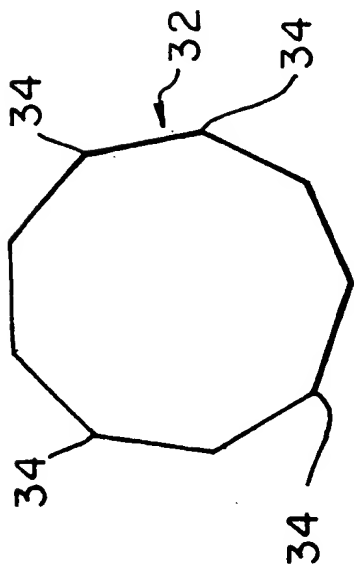


FIG. 4

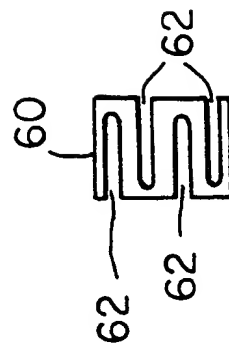
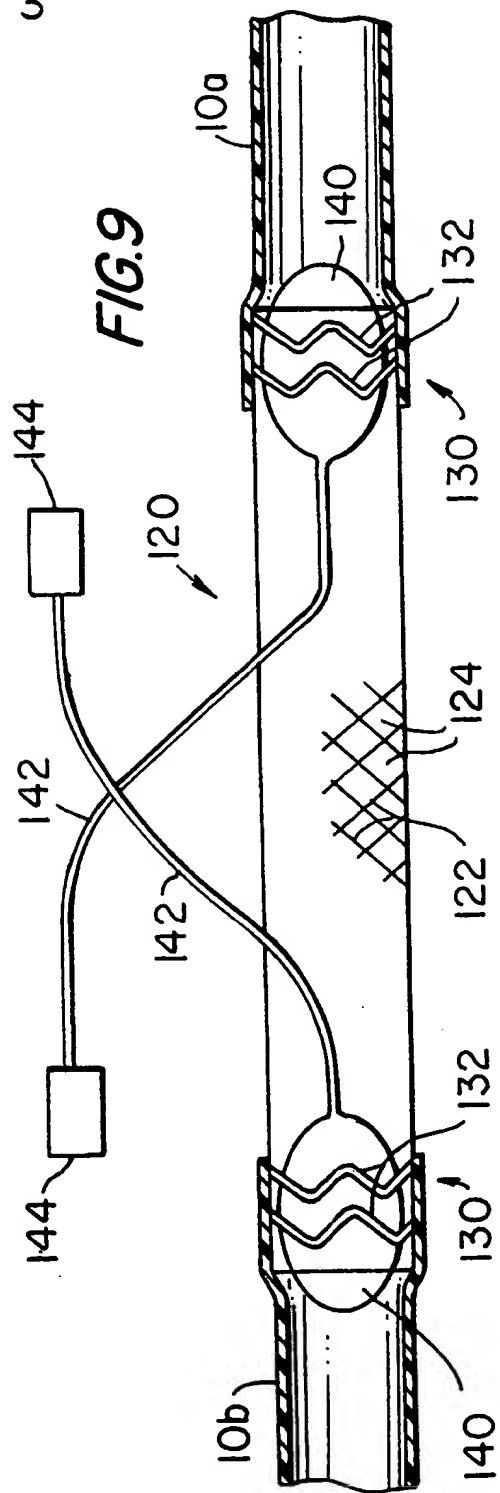
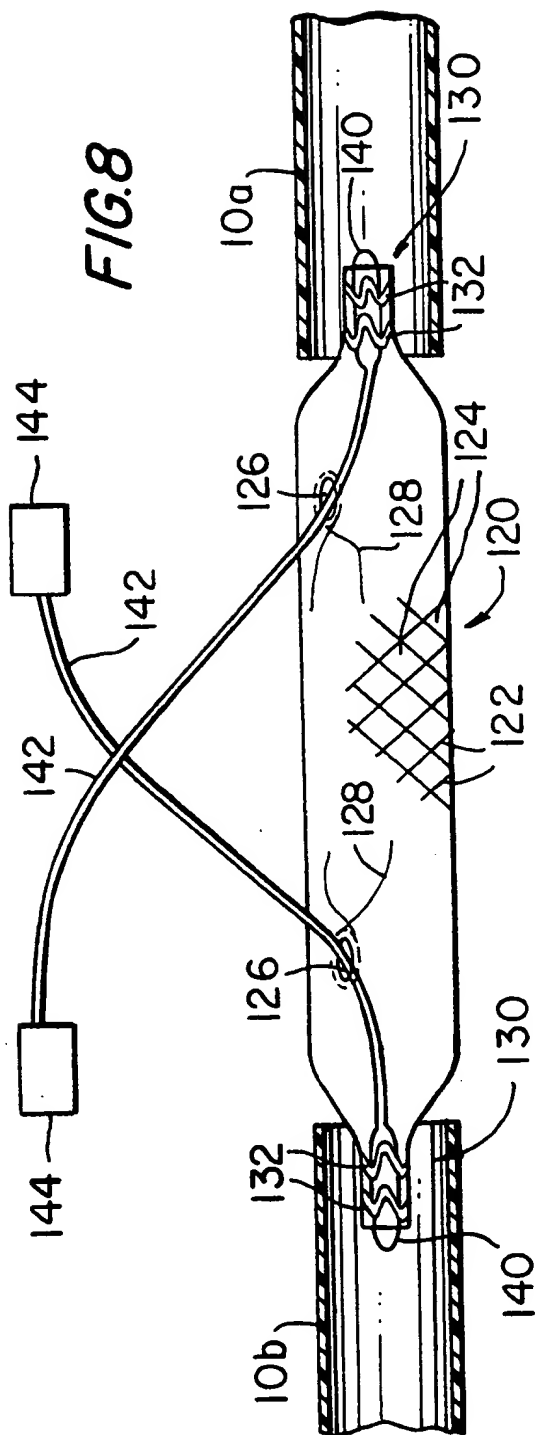


FIG. 7



FIG. 6

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INTERNATIONAL SEARCH REPORT

Intern. Application No

PCT/US 97/20060

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 269 104 A (LAZIM TAHA ROUDAN ; LAZIM TAHA ROUDAN (MY)) 2 February 1994 see page 14, last paragraph - page 16, paragraph 3; claims 2-4; figures ---	1,2,6, 12,13, 16,17, 19-26, 28,29, 31,35,36
X	WO 96 22745 A (SCHNEIDER USA INC ; INDIANA UNIVERSITY FOUNDATION (US); UNIV JOHNS) 1 August 1996 see page 5, line 17 - page 9, line 16; figures --- -/--	1-4,6,9, 10,12, 13,16, 17,19, 20,24, 28-31, 35,36,38

☒ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search

24 March 1998

Date of mailing of the international search report

01.04.98

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/20060

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 14808 A (ADVANCED CARDIOVASCULAR SYSTEM) 23 May 1996	1,2,6-8, 12-15, 19,20, 24,28, 31,32,35
A	see page 6, line 2 - line 17; figures see page 11, line 20 - page 12, line 24 -----	3,9,10, 33,36,37

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/20060

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 39-49
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. .onal Application No

PCT/US 97/20060

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2269104 A	02-02-94	NONE	
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WO 9622745 A	01-08-96	US 5591226 A	07-01-97
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WO 9614808 A	23-05-96	EP 0790810 A	27-08-97
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